

K111902

TORNIER

Implants Chirurgicaux

Summary of Safety and Effectiveness information *Special 510(k) Premarket Notification – Aequalis Shoulder System*

Date prepared: October 14th, 2011

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) Device name

Trade name: Aequalis Shoulder System
Common name: Total shoulder prosthesis
Classification name: 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier
 Rue Doyen Gosse
 38330 Saint Ismier - France

3) Applicant

Tornier, Inc.
 7701 France avenue South
 Edina MN 55345 - USA

4) Company contact

Tornier
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5) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: KWS

6) Equivalent / Predicate device

Aequalis Shoulder System, Tornier, K952928, K994392, K060209 and K063081
 Affiniti Total and Hemi-Shoulder System, Tornier, Inc., K060988 and K103007



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7) Device description

The usual goal of total shoulder and hemi-arthroplasty replacement of the shoulder is to restore the shoulder joint to its best working condition and to reduce or eliminate pain. The Aequalis Shoulder System is intended to accomplish these goals.

It consists in a humeral stem and a humeral head. With these systems the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease or injury. Thus the Aequalis Shoulder Fracture System is intended for use as a total shoulder replacement system, or as a hemi-shoulder.

The modular nature of the system allows for the later conversion of a primary hemi-arthroplasty to a total shoulder replacement.

The present device modification submission consists in the addition of a new glenoid system, named Tornier Glenoid, to the current cleared model. The Tornier Glenoid system is a comprehensive offering that includes a variety of anchorage options such as a keel, standard peg and CortiLoc™ peg available in a variety of sizes.

The Tornier Glenoid has been designed to be compatible with the Aequalis, Affiniti and Ascend humeral head systems in certain combinations.

The new Tornier Glenoid completes the Tornier range of glenoid implants.

Tornier Glenoid component is intended for cemented use only.

8) Materials

The glenoid implant is manufactured of ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2 and from chromium cobalt alloy (radio wire) according to ISO 5832-7.

9) Indications for use

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthritis, post-traumatic arthrosis. Primary or secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture

Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable. Revision surgery when other treatments or devices have failed.

The Aequalis monobloc stem is cemented use.

The Aequalis Press-Fit is for uncemented use.

Glenoid component is for cemented use.



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10) Summary of technological characteristics

Main features or system characteristics	Tornier Glenoid System	Aequalis Shoulder System	Affiniti TM Shoulder System
Materials	UHMWPE + CoCr	UHMWPE + CoCr	UHMWPE
Shape	Pear shape	Pear shape	Pear shape
Method of fixation	cemented	cemented	cemented
Sizes	4 sizes (S, M, L and XL) for the pegged and keeled glenoid	Function of the range: 3 to 6 sizes for the pegged and keeled glenoid	5 sizes (40, 44, 48, 52 and 56)
Anchorage	4 pegs or keel	4 pegs or keel	4 pegs or keel
Polyethylene thickness	4mm	2 to 4mm	4mm
Indications for use	Total Shoulder replacement	Total Shoulder replacement	Total Shoulder replacement
Terminal sterilization	Gamma	Gamma	Gamma
Manufacturer	Tornier	Tornier	Tornier Inc.
K-number	pending	K952928 K994392 K060209 K063081	K060988 K103007

The indications for use, the technical characteristics (materials, manufacturing principle and method of fixation), the packaging and the sterilization process of the new Tornier Glenoid are similar or identical to the predicate devices.

11) Non-clinical testing

Non-clinical testing was not necessary to determinate substantial equivalence between the new Tornier Glenoid and the cited predicate devices regarding:

- The indications for use of the new Tornier Glenoid are identical to the indications for use of the predicate Aequalis Shoulder System (K952928, K994392, K060209 and K063081) and are very similar with the other predicate the AffinitiTM Shoulder System (K060988, K103007).
- The intended use of the new Tornier Glenoid are identical to the intended use of predicates Aequalis Shoulder System (K952928, K994392, K060209 and K063081) and the AffinitiTM Shoulder System (K060988, K103007).
- The raw materials of the new components of the Tornier Glenoid are identical to the raw materials of predicates Aequalis Shoulder System (K952928, K994392, K060209 and K063081) and the AffinitiTM Shoulder System (K060988, K103007).

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- The fixation method of the new Tornier Glenoid is identical to the fixation method of the predicate components of the Aequalis Shoulder System (K952928, K994392, K060209 and K063081) and the Affiniti™ Shoulder System (K060988, K103007).

The modifications made to the proposed Aequalis Shoulder System, addition of a new Tornier Glenoid range, were verified and validated by performing non-clinical testing:

- Bench test:
 - o Range of motion
 - o Preliminary testings - peripheral and central pegs design - influence of cement compaction & cement layer thickness
 - o Pull out & shear testings on Tornier Glenoids
 - o Subluxation and loosening tests on glenoid components

The results of those evaluations allow us to conclude that the proposed new Tornier Glenoid described in this submission does not induce any new or higher risk compared to the predicate devices and therefore both devices (proposed and predicate) are substantially equivalent.

12) Substantial equivalence conclusion

Based upon this comparative study, substantial equivalence of the new Tornier Glenoid to the already cleared components of the predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The Tornier Glenoid are compared to the predicate devices.
- The Tornier Glenoid have the same intended use as the Aequalis shoulder System and the Affiniti™ Shoulder System are very similar indications for use.
- Major technological characteristics are equivalent between the Tornier Glenoid and the predicate devices:
 - Equivalence of general features
 - Equivalent polyethylene thickness
 - Equivalent materials
 - Equivalent means of fixation
 - Equivalent prosthetic dimensions

Therefore, in light of the above information, the company believes that the Tornier Glenoid may be cleared via the 510(k) notification process for use as total shoulder prosthesis.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Tornier, Inc.
% Ms. Severine Bonneton
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NOV - 3 2011

Re: K111902
Trade/Device Name: Aequalis Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: October 14, 2011
Received: October 17, 2011

Dear Ms. Bonneton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111902

Device Name: Aequalis Shoulder System

Indications For Use:

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthritis, post-traumatic arthrosis. Primary or secondary necrosis of the humeral head
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Revision surgery when other treatments or devices have failed.

The Aequalis monobloc stem is cemented use.

The Aequalis Press-Fit is for uncemented use.

Glenoid component is for cemented use.

Prescription Use ☒ X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Congurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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